

NOTE: REDACTIONS TO THIS DOCUMENT HAVE BEEN MADE UNDER FOIA EXEMPTION B6

United States Government  
Interagency Agreement (IAA) – Agreement Between Federal Agencies  
General Terms and Conditions (GT&C) Section

IAA Number APH-HQ-15-0186 - 0000 -  
GT&C # Order # Amendment/Mod #

DEPARTMENT AND/OR AGENCY			
1.	Requesting Agency of Products/Services	Servicing Agency Providing Products/Services	
	Name	USDA, APHIS, BRS	U.S. EPA
	Address	4700 River Rd., Unit 55 Riverdale, MD 20737	1200 Pennsylvania Ave, NW Washington, DC 20460
2. Servicing Agency Agreement Tracking Number (Optional) <u>HQ9915115320</u> <u>APHIS Agreement No. 16-2000-0092-IA</u>			
3. Assisted Acquisition Agreement Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>			
4. GT&C Action (Check action being taken) <input checked="" type="checkbox"/> New <input type="checkbox"/> Amendment – Complete only the GT&C blocks being changed and explain the changes being made.  <input type="checkbox"/> Cancellation – Provide a brief explanation for the IAA cancellation and complete the effective End Date.			
5. Agreement Period Start Date <u>05-01-2016</u> End Date <u>09-28-2017</u> of IAA or effective cancellation date MM-DD-YYYY MM-DD-YYYY			
6. Recurring Agreement (Check One) A Recurring Agreement will continue, unless a notice to discontinue is received. Yes <input type="checkbox"/> If Yes, is this an: Annual Renewal <input type="checkbox"/> Other Renewal <input checked="" type="checkbox"/> State the other renewal period: <u>No renewal or recurrence planned</u> No <input checked="" type="checkbox"/>			
7. Agreement Type (Check One) <input checked="" type="checkbox"/> Single Order IAA <input type="checkbox"/> Multiple Order IAA			
8. Are Advance Payments Allowed for this IAA (Check One) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes is checked, enter Requesting Agency's Statutory Authority Title and Citation			
Note: Specific advance amounts will be captured on each related Order.			

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**13. Restrictions (Optional)** (State and/or attach unique requirements and/or mission specific restrictions specific to this IAA).  
All funds must be obligated by the servicing agency by September 30, 2016

**14. Assisted Acquisition Small Business Credit Clause** (The Servicing Agency will allocate the socio-economic credit to the Requesting Agency for any contract actions it has executed on behalf of the Requesting Agency.)

**15. Disputes:** Disputes related to this IAA shall be resolved in accordance with instructions provided in the Treasury Financial Manual (TFM) Volume I, Part 2, Chapter 4700, Appendix 10; Intragovernmental Business Rules.

**16. Termination** (Insert the number of days that this IAA may be terminated by written notice by either the Requesting or Servicing Agency.)

If this agreement is canceled, any implementing contract/order may also be canceled. If the IAA is terminated, the agencies shall agree to the terms of the termination, including costs attributable to each party and the disposition of awarded and pending actions.

If the Servicing Agency incurs costs due to the Requesting Agency's failure to give the requisite notice of its intent to terminate the IAA, the Requesting Agency shall pay any actual costs incurred by the Servicing Agency as a result of the delay in notification, provided such costs are directly attributable to the failure to give notice.

**17. Assisted Acquisition Agreements – Requesting Agency's Organizations Authorized To Request Acquisition Assistance for this IAA.** (State or attach a list of Requesting Agency's organizations authorized to request acquisition assistance for this IAA.)

**18. Assisted Acquisition Agreements – Servicing Agency's Organizations authorized to Provide Acquisition Assistance for this IAA.** (State or attach a list of Servicing Agency's organizations authorized to provide acquisition for this IAA.)  
EPA/OCSP will provide a Task Order COR. EPA/OAM/CPOD will provide the support of the Contracting Officer for the NAS contract.

**19. Requesting Agency Clause(s) (Optional)** (State and/or attach any additional Requesting Agency clauses.)



United States Government  
Interagency Agreement (IAA) – Agreement Between Federal Agencies  
Order Requirements and Funding Information (Order) Section

IAA Number APH-HQ-15-0186

GT&C # \_\_\_\_\_

Order # \_\_\_\_\_ Amendment/Mod # \_\_\_\_\_

Servicing Agency's Agreement

Tracking Number (Optional) HQ9915115320

**PRIMARY ORGANIZATION/OFFICE INFORMATION**

<b>24.</b>	<b>Requesting Agency</b>	<b>Servicing Agency</b>
Primary Organization/Office Name	USDA, APHIS, BRS	Environmental Protection Agency
Responsible Organization/Office Address	4700 River Road, Unit 55 Riverdale, MD 20737	1200 Pennsylvania Ave, NW Washington, DC 20460

**ORDER/REQUIREMENTS INFORMATION**

**25. Order Action (Check One)**

☒ New

☐ **Modification (Mod)** – List affected Order blocks being changed and explains the changes being made. For Example: for a performance period mod, state new performance period for this Order in Block 27. **Fill out the Funding Modification Summary by Line (Block 26) if the mod involves adding, deleting or changing Funding for an Order Line.**

☐ **Cancellation** – Provide a brief explanation for Order cancellation and fill in the Performance Period End Date for the effective cancellation date.

<b>26. Funding Modification Summary by Line</b>	Line # <u>1</u>	Line # _____	Line # _____	Total of All Other Lines (attach funding details)	Total
Original Line Funding	\$ 157,500.00	\$	\$	\$	\$157,500.00
Cumulative Funding Changes From Prior Mods [addition (+) or reduction (-)]	\$	\$	\$	\$	\$ 0.00
Funding Change for This Mod	\$	\$	\$	\$	\$ 0.00
<b>TOTAL Modified Obligation</b>	<b>\$ 157,500.00</b>	<b>\$ 0.00</b>	<b>\$ 0.00</b>	<b>\$ 0.00</b>	<b>\$157,500.00</b>
Total Advance Amount (-)	\$	\$	\$	\$	\$ 0.00
<b>Net Modified Amount Due</b>	<b>\$ 157,500.00</b>	<b>\$ 0.00</b>	<b>\$ 0.00</b>	<b>\$ 0.00</b>	<b>\$157,500.00</b>

**27. Performance Period**

Start Date

05-01-2016

End Date

09-28-2017

For a performance period mod, insert the start and end dates that reflect the new performance period.

MM-DD-YYYY

MM-DD-YYYY

# IAA Order

IAA Number APH-HQ-15-0186  
GT&C # \_\_\_\_\_

Order # \_\_\_\_\_ Amendment/Mod # \_\_\_\_\_

Servicing Agency's Agreement  
Tracking Number (Optional) HQ9915115320

## 29. Advance Information (Complete Block 29 if the Advance Payment for Products/Services was checked "Yes" on the GT&C.)

Total Advance Amount for the Order \$ \_\_\_\_\_ [All Order Line advance amounts (Block 28) must sum to this total.]

Revenue Recognition Methodology (according to SFFAS 7) (Identify the Revenue Recognition Methodology that will be used to account for the Requesting Agency's expense and the Servicing Agency's revenue)

- ☐ Straight-line – Provide amount to be accrued \$ \_\_\_\_\_ and Number of Months \_\_\_\_\_
- ☒ Accrual Per Work Completed – Identify the accounting posting period:
- ☒ Monthly per work completed & invoiced
- ☐ Other – Explain other regular period (bimonthly, quarterly, etc.) for posting accruals and how the accrual amounts will be communicated if other than billed. \_\_\_\_\_

30. Total Net Order Amount: \$ 157,500.00

[All Order Line Net Amounts Due for reimbursable agreements and Net Total Costs for Assisted Acquisition Agreements (Block 28) must sum to this total.]

## 31. Attachments (State or list attachments.)

- ☐ Key project and/or acquisition milestones (Optional except for Assisted Acquisition Agreements)
- Publication of Final Study Report

☐ Other Attachments (Optional)

SOW  
Whilehouse Memo

## BILLING & PAYMENT INFORMATION

32. Payment Method (Check One) [Intra-governmental Payment and Collection (IPAC) is the Preferred Method.]  
If IPAC is used, the payment method must agree with the IPAC Trading Partner Agreement (TPA).

- ☐ Requesting Agency Initiated IPAC ☒ Servicing Agency Initiated IPAC
- ☐ Credit Card ☐ Other – Explain other payment method and reasoning \_\_\_\_\_

## 33. Billing Frequency (Check One)

[An Invoice must be submitted by the Servicing Agency and accepted by the Requesting Agency BEFORE funds are reimbursed (i.e., via IPAC transaction)]

- ☒ Monthly ☐ Quarterly ☐ Other Billing Frequency (include explanation) \_\_\_\_\_

## 34. Payment Terms (Check One)

IPAC

- ☐ 7 days ☒ Other Payment Terms (include explanation): \_\_\_\_\_



# IAA Order

IAA Number APH-HQ-15-0186  
GT&C # \_\_\_\_\_

Order # \_\_\_\_\_ Amendment/Mod # \_\_\_\_\_

Servicing Agency's Agreement  
Tracking Number (Optional) HQ9915115320

CONTACT INFORMATION		
<b>FINANCE OFFICE Points of Contact (POCs)</b>		
The finance office points of contact must ensure that the payment (Requesting Agency), billing (Servicing Agency), and advance/accounting information are accurate and timely for this Order.		
<b>39.</b>	<b>Requesting Agency (Payment Office)</b>	<b>Servicing Agency (Billing Office)</b>
Name	Bill Hughes	
Title	Financial Manager	
Office Address	4700 River Road Riverdale, MD 20737	
Telephone Number	(301) 851-3914	
Fax Number		
Email Address	William.D.Hughes@aphis.usda.gov	
Signature & Date (Optional)	WILLIAM HUGHES	
<b>40. ADDITIONAL Points of Contacts (POCs) (as determined by each Agency)</b>		
This may include CONTRACTING Office Points of Contact (POCs).		
	<b>Requesting Agency</b>	<b>Servicing Agency</b>
<b>Name</b>	Eileen Berke	
<b>Title</b>	Management Analyst	
<b>Office Address</b>	4700 River Road, Unit 55 Riverdale, MD 20737	
<b>Telephone Number</b>	(301) 851-2856	
<b>Fax Number</b>		
<b>Email Address</b>	Eileen.M.Berke@aphis.usda.gov	
<b>Signature &amp; Date (Optional)</b>		
<b>Name</b>		
<b>Title</b>		
<b>Office Address</b>		
<b>Telephone Number</b>		
<b>Fax Number</b>		
<b>Email Address</b>		
<b>Signature &amp; Date (Optional)</b>		
<b>Name</b>		
<b>Title</b>		
<b>Office Address</b>		
<b>Telephone Number</b>		
<b>Fax Number</b>		
<b>Email Address</b>		
<b>Signature &amp; Date (Optional)</b>		

frameworks for risk assessment and (2) areas in which the risks or lack of risks relating to the products of biotechnology are well understood.”

This memorandum recognized that advances in science and technology “have dramatically altered the biotechnology landscape since the 1992 update of the CF.” For example, the Coordinated Framework focused on products of biotechnology created with recombinant DNA (rDNA) and *in vitro* technologies. Now genetic engineering includes both *in vitro* and *in vivo* technologies, and along with rDNA, there have been advances in the ability to synthesize DNA and to use genome editing techniques to engineer organisms such as plants, animals, and microbes. Regulators, policy makers, and practitioners will benefit from a sound understanding of the techniques currently in use and under development for modifying and adapting organisms and how these techniques are and might be applied (separately and in combination) for product development. This could include products with applications in energy, biomanufacturing, agriculture, and environmental protection, such as “ready to burn” liquid fuels produced directly from CO<sub>2</sub>, bio-based chemicals, tailored food products to meet specialized dietary requirements, and novel biosensors for real-time monitoring of the environment.

Based on this “horizon scanning,” an assessment of the risks and uncertainties that might be associated with the future products of biotechnology using these and other techniques would contribute to advancing the U.S. regulatory system to address future needs. This evaluation would include whether or to what extent products of these technological advances and current or envisioned applications introduce new types of risks or whether they are likely to mitigate risks.

Statutory Authority for this IA is under TSCA Section 10 (15 U.S.C. 2609).

#### **Period of Performance**

The Period of Performance for this IA is for approximately 2 years. The IA shall be initiated on the date of award and terminate on September 28, 2017. Upon mutual agreement of the parties, in writing, this IA may be terminated, in whole or in part, at any time before the date of expiration. However, it is understood that EPA will obligate the funds to a non-severable services contract with the National Academy of Science (NAS) #EP-C-14-005, TO#10, and after such legal obligation occurs, the funds will not be available for re-imbursement except as unspent funds at the end of the period of performance.

#### **Statement of Task**

EPA will direct a NAS to form a committee that will produce a consensus report designed to answer the questions “What will the likely future products of biotechnology be over the next 5-10 years? What scientific capabilities, tools and/or expertise may be needed by the regulatory agencies to ensure they make efficient and sound evaluations of the likely future products of biotechnology?”

The committee will:

- Describe the major advances and the potential new types of biotechnology products likely to emerge over the next 5-10 years.



In accordance with Section 15 of FACA, the Academy will submit to EPA a certification that the policies and procedures of the Academy that implement Section 15 of FACA have been substantially complied with in the performance of the contract. EPA will provide a copy this certification with USDA and FDA.

### **Communications**

It is important that EPA, USDA, and FDA representatives work closely to execute this IA. After NAS begins work agencies EPA will provide monthly progress updates as forwarded from the NAS. The EPA will notify USDA within 30 days of any change in the Project Officer. Likewise, USDA will notify the EPA within 30 days of any change in the Government Technical Representative (GTR) or PO.

FDA will promptly notify the EPA Project Officer of any concerns associated with the reporting format and may request changes to increase effectiveness. The EPA Project Officer will notify the FDA GTR/PO of the timeframe in which the situation will be resolved, whether the request can be accommodated with funding available, or will provide explanation as to why the concerns may not be addressed.

### **Funding**

In accordance with the White House directive and mutual agreement of agency principals, approximately equal funds, approximately \$315K, are to be provided by USDA, EPA, and FDA in accordance with their approximately equal interest in the results of the study.

Funding will be provided by the requesting agencies (USDA and FDA) will provide funding through the IA. The purpose of this funding is to cover the full amount of the anticipated contract obligation where the servicing agency (EPA) and EPA's indirect costs for managing the Task Order with NAS. EPA will issue and manage the Task Order/Contract with NAS.

### **Points of Contact**

#### U.S. Food and Drug Administration

#### USDA Agricultural Research Service

*Funds-Out IA Project Officer*  
Sidney Abel  
Assistant Deputy Administrator  
U.S. Department of Agriculture  
Animal and Plant Health Inspection Service  
4700 River Rd, Unit 89  
Riverdale Park, MD 20737  
Telephone: (301) 851-3947  
Email: Sidney.W.Abel@aphis.usda.gov



Interagency Agreement  
Shared Service Center **IASSC**  
*Customer Centered, Service Oriented*

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Interagency Agreement Shared Service Center

**EAST**  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Mail Code: 3903R  
Washington, D.C. 20460

**WEST**  
Park Place Building  
1200 Sixth Avenue, Suite 900  
Mail Stop: OMP-145  
Seattle, WA 98101

EPA Reference: RW-012-92453401-0  
USDA Reference: APH-HQ-15-0186

Dear Interagency Agreement (IA) Recipient:

Attached is an electronically signed pdf of a new or amended IA between EPA and your Federal Agency. **Please note a signature is needed from your authorizing official in box 41 of the EPA 1610 form for this IA to be obligated and legally binding.**

If you wish to accept the agreement, please have your authorizing official sign box 41 of the EPA 1610-1 form and return to us, a signed copy within 3 weeks of this date.

Please return the signed IA using one of the following methods:

- Pdf scan to IA specialist: [connell.lenore@epa.gov](mailto:connell.lenore@epa.gov)
- Fax to 202-565-2470 (Attn: Lenore Connell)
- Mail to: Lenore Connell (Mailcode 3903R), US EPA, 1200 Pennsylvania Avenue NW, Washington DC 20460

If you have questions, please contact the EPA Project Officer listed in box 14 or the IA Specialist listed in box 6 of the attached EPA 1610 form.

Sincerely,

Frank Roth, Chief  
IASSC EAST  
FISB/GIAMD

Enclosure

cc: Bryan Lobar (HQ)



Part II - Approved Budget				EPA IAG Identification Number RW-012-92453401 - 0
31. Budget Categories	Itemization of All Previous Actions	Itemization of This Action	In-Kind Itemization of This Action	Itemization of Total Project Cost to Date
(a) Personnel				\$0.00
(b) Fringe Benefits				\$0.00
(c) Travel				\$0.00
(d) Equipment				\$0.00
(e) Supplies				\$0.00
(f) Procurement / Assistance		\$147,749.00		\$147,749.00
(g) Construction				\$0.00
(h) Other				\$0.00
(i) Total Direct Charges	\$0.00	\$147,749.00	\$0.00	\$147,749.00
(j) Indirect Costs:	\$0.00	\$9,751.00		\$9,751.00
Charged - Amount Rate: 6.6% Base: \$ Not Charged: Funds-In: Not charged by EPA Amount \$				
(k) Total (EPA Share 0.00 %) (Other Agency Share 100.00 %)	\$0.00	\$157,500.00	\$0.00	\$157,500.00
32. How was the IDC Base calculated?				
33. Is equipment authorized to be furnished by EPA or leased, purchased, or rented with EPA funds? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Identify all equipment costing \$1,000 or more)				
34. Are any of these funds being used on Procure/Assistance agreements? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No				
Type of Procure/Assistance Agreement <input type="checkbox"/> Contract				
Contractor/Recipient Name (if known)	Total Procure/Assistance Amount Under This Project		Percent Funded by EPA (if known)	
National Academy of Science	147749.00 Total \$ 147,749.00		0	
Part III - Funding Methods and Billing Instructions				
(Note: EPA Agency Location Code (ALC) - 68010727)				
<input type="checkbox"/> Disbursement Agreement	Request for repayment of actual costs must be itemized on SF 1080 and submitted to the Financial Management Office, Cincinnati, OH 45268-7002:			
<input type="checkbox"/> Repayment	<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Upon Completion of Work			
<input type="checkbox"/> Advance	Only available for use by Federal agencies on working capital fund or with appropriate justification of need for this type of payment method. Unexpended funds at completion of work will be returned to EPA. Quarterly cost reports will be forwarded to the Financial Management Center, EPA, Cincinnati, OH 45268-7002.			
<input type="checkbox"/> Allocation Transfer-Out	Used to transfer obligational authority or transfer of function between Federal agencies. Must receive prior approval by the Office of Comptroller, Budget Division, Budget Formulation and Control Branch, EPA Hdqtrs. Forward appropriate reports to the Financial Reports and Analysis Branch, Financial Management Division, PM-226F, EPA, Washington, DC 20460.			
36. <input checked="" type="checkbox"/> Reimbursement Agreement	<input checked="" type="checkbox"/> Repayment <input type="checkbox"/> Advance			
Allocation Transfer-In				
Other Agency's Billing Address (include ALC or Station Symbol Number)			Other Agency's Billing Instructions and Frequency	
			Other Agency TAS <span style="background-color: black; color: black;">XXXXXXXXXX</span> B(6)	

### **Administrative Conditions**

#### **1. Resolution of Disagreements**

Should disagreements arise on the interpretation of the provisions of this agreement or amendments and/or revisions thereto, that cannot be resolved at the operating level, the area(s) of disagreement shall be stated in writing by each party and presented to the other party for consideration. If agreement or interpretation is not reached within 30 days, the parties shall forward the written presentation of the disagreement to respective higher officials for appropriate resolution.

If a dispute related to funding remains unresolved for more than 30 calendar days after the parties have engaged in an escalation of the dispute, disputes will be resolved in accordance with instructions provided in the Treasury Financial Manual (TFM) Volume I, Part 2, Chapter 4700, Appendix 10, available at <http://www.fms.treas.gov/tfm/index.html>.

#### **2. Cost Collection Upon Cancellation**

If the IA recipient cancels the agreement, the Environmental Protection Agency is authorized to collect costs incurred prior to the cancellation of the agreement, plus termination costs, up to the total payment amount provided for under the agreement.

### **Programmatic Conditions**

Contract bills are to be distributed proportionally by source agency

Unpaid funds are to be re-imbursed to the requesting agency after contract closeout.

See attached IA Statement of Work for additional Terms and Conditions.



This memorandum shall be implemented consistent with applicable law, Executive Order 13563, Executive Order 13610, and the 2011 "Principles for Regulation and Oversight of Emerging Technologies" memorandum.<sup>2, 3, 4</sup> Through those policies, this Administration has sought regulatory approaches that protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers. These principles must now be applied to updating the regulatory framework and systems that regulate the products of biotechnology.

## **Background**

In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (CF),<sup>5</sup> which describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The CF sought to achieve a balance between regulation adequate to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation. In 1992, OSTP issued an update to the CF<sup>6</sup> that sets forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment. The update affirmed that Federal oversight should focus on the characteristics of the product and the environment into which it is being introduced, rather than the process by which the product is created.

Each of the Federal regulatory agencies with jurisdiction over the products of biotechnology has developed regulations and guidance documents to implement its authority under existing laws, resulting in a complex system for assessing and managing health and environmental risks of the products of biotechnology. While the current regulatory system for the products of biotechnology effectively protects health and the environment, in some cases unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes have arisen. These costs and burdens have limited the ability of small and mid-sized companies to navigate the regulatory process and of the public to understand easily how the safety of these products is assured; and, accordingly, they have the potential to reduce economic growth, innovation, and competitiveness.

Advances in science and technology, moreover, have dramatically altered the biotechnology landscape since the 1992 update of the CF. Such advances can enable the development of products that were not previously possible. A further update of the CF is needed to facilitate the appropriate Federal oversight by the regulatory system and increase transparency, while continuing to provide a framework for advancing innovation.

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<sup>3</sup> "Identifying and Reducing Regulatory Barriers", Executive Order 13610, January 10, 2012.

<sup>4</sup> "Principles for Regulation and Oversight of Emerging Technologies", Memorandum for the Heads of Departments and Agencies, March 11, 2011.

<sup>5</sup> [http://www.aphis.usda.gov/brs/fcdregister/coordinated\\_framework.pdf](http://www.aphis.usda.gov/brs/fcdregister/coordinated_framework.pdf)

<sup>6</sup> [https://www.whitehouse.gov/sites/default/files/microsites/ostp/57\\_fcd\\_reg\\_6753\\_1992.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fcd_reg_6753_1992.pdf)

- (iii) a standard mechanism for communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function; and
  - (iv) the mechanism and timeline for regularly reviewing, and updating as appropriate, the CF to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products; and
- (b) develop a long-term strategy to ensure that the Federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, maintaining public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens by:
- (i) developing a plan for periodic formal horizon-scanning assessments of new biotechnology products to ensure that regulatory agencies are prepared for future products well before they reach the regulatory system;
  - (ii) working with other Federal agencies, as appropriate, to develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities with regard to the assessment of biotechnology products, and to reflect these priorities in agency budget submissions starting with the fiscal year (FY) 2017 budget;
  - (iii) ensuring that product evaluations are risk-based and grounded in the best science available, including regularly adjusting regulatory activities based on experience with specific products and the environments into which those products have been introduced;
  - (iv) establishing a timetable and mechanisms to work with stakeholders to identify impediments to innovation, focusing on building new, and augmenting existing, stakeholder collaborations to inform efforts, increase transparency, streamline processes, reduce costs and response times, and ensure the protection of health and the environment;
  - (v) coordinating the development of tools and mechanisms for assisting small businesses developing biotechnology products to navigate the regulatory system;
  - (vi) identifying changes to authorities, regulations, and policies, if any, that could improve agencies' abilities to assess expeditiously the potential impacts and risks arising from future products of biotechnology and to ensure the transparency, predictability, and efficiency of regulatory oversight for such products;
  - (vii) initiating development of a modernized, user-friendly set of tools for presenting the regulatory agencies' authorities, practices, and bases for decision making for the regulation of biotechnology products to the public, including digital services to improve the interactions between the FDA, EPA, USDA, the general public, and product developers and



U.S. Environmental Protection Agency

*Project Officer*

Bryan Iobar  
U.S. Environmental Protection Agency  
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Environmental Assistance Division  
1200 Pennsylvania Avenue, NW (7404T)  
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Email: [lobar.bryan@epa.gov](mailto:lobar.bryan@epa.gov)

*Alt Project Officer*

Iris Camacho  
U.S. Environmental Protection Agency  
Office of Pollution Prevention and Toxics  
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*Government Technical Representatives*

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Jeff Morris, Deputy Director (OPPT)  
U.S. Environmental Protection Agency  
Office of Pollution Prevention and Toxics (OPPT)  
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